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Bart Eggen, Director
Office of Certification and Enforcement
Department of Health
P.O. Box 47852
310 Israel Road
Tumwater, WA 98504

Dear Mr Eggen and members of the DOH:

Regarding: Development of CON rules for Elective PCI in hospitals without on-site cardiac surgery.

I am an interventional cardiologist who has practiced in Mount Vernon WA for over 20 years. Our cardiac catheterization laboratory at Skagit Valley Hospital has consistently maintained a high quality (per COAP statistics), low volume (<200/yr) acute intervention program for over 15 years. Many lives have been saved by our interventions during heart attacks (acute MI), and the community has come to rely on us for this service. We are in grave danger of losing this program despite our unanimous community support. The guidelines proposed report to the DOH by Health Management Associates would put the "nail in the coffin" for acute MI intervention in our county of 100,000 Washingtonians. Maintaining staff and interventional cardiologists is simply impossible in a community hospital treating only acute myocardial infarction (AMI). Current interventional cardiologists will simply not work 30 miles from the nearest hospital where they perform elective interventions and are continually frustrated and embarrassed by their inability to provide efficient and effective treatment locally.

I concur with letters of criticism already on file from Health Facilities Planning and Development (on behalf of multiple hospitals including my own), Dr Rubin Maiden of Eastside Cardiology Associates, Scott Laubish of Peace Health Saint Johns Medical Center, and of Senator Jim Katama and Representative Dawn Morell and will not repeat these comments. I am completely convinced that elective PCI can be performed in hospitals without surgical backup in selected patients and have extensive experience in both settings on which to base my opinion. The point of this letter is to bring to the table the perspective of our unique community's experience.

Errors of commission vs. errors of omission:

It is easier to determine the frequency of complications resulting from a procedure (errors of commission) than mortality/morbidity from delay or lack of access to that procedure (errors of omission). The report to the DOH focuses on the former, but completely fails to address the later. In fact, if implemented, the proposed rules would lead to many more "errors of omission" due to reduced access.

Yes, every procedure has a risk, yet this must be weighed against the risk of not performing the procedure. The fact that there are few studies of the effects of these errors of omission does not make the issue unimportant, just difficult to analyze statistically. The issue currently before the DOH concerns elective intervention however, this cannot be viewed without appreciating the effects the rules would have on intervention for acute MI. In a community like ours we cannot continue to perform one without the other.

In October, 2007 the NEJM published a review of Acute intervention for MI (1). This contains an instructive table showing an additional mortality of 6 per 1000 acute MI patients for every 15 minute delay in intervention. If a community like ours is unable to continue our program, delaying intervention 45 minutes to travel the additional 30+ miles to the nearest hospital with cardiac surgery capabilities and transition care to new providers we would expect to see 18 additional deaths per 1000 MIs in our community; added to this are the complications of having surviving patients with more damaged hearts from delayed intervention. The validity of these estimates is obvious to all of us who practice on the "front lines".

There are many more potential errors of omission, less quantifiable but equally important, caused by the need to transfer patients for "elective intervention" including delayed diagnosis and treatment, bleeding risks, infection risks from having catheters in arteries for prolonged periods, loss of community expertise in management of late complications and on and on. Many of these have been commented on in prior letters.

Volume equals quality:

The use of volume standards as a surrogate for quality derives from the fact that it is easily measured with publicly available data. There have always been high volume hospitals with poor outcomes, and small volume hospitals with good outcomes. It has just been difficult to find quantifiable quality indicators. *Good outcomes equals "* ***quality****", not volume!* Current programs such as our COAP initiative in Washington and the ACC database are far more sophisticated ways to understand program performance and patient outcomes. The DOH should rely on these more modern methods instead. Our program has always been low volume, but our outcomes exceptional. Does it make sense to have our patients die because it is difficult to evaluate our performance with a single statistic?

I believe the Washington legislature appreciated the danger of losing access to intervention in our community when they asked the DOH to develop a CON process to meet this need. The current proposed rules would have the opposite effect. We have absolute faith in our ability to continue and improve the quality of care to the patients of Skagit and Island counties *only* if the CON rules developed by the DOH allow us to do so.

Sincerely,

Richard Gubner MDFACC

Mount Vernon, WA

(1) Nallamouthu, B.K. et al, Time to Treatment in Primary Percutaneous Coronary Intervention. N Engl J Med 2007;357: 1631-8